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## Description

The present invention relates to devices for controlling urinary incontinence and to vaginal and rectal prolapse in females. Particularly, the invention relates to a device which may be removably inserted into the vagina.

Female urinary incontinence is a common problem and is particularly prevalent where damage to the bladder or neck of the bladder has occurred during child birth. In elderly female patients, urinary incontinence is widespread.

In normal continent patients, in the erect posture, there is no descent of the bladder neck below the pelvic floor muscle, thereby equal distribution of intra-abdominal pressure to the bladder and bladder neck and pelvic urethra occurs, and continence is maintained. However, in stress incontinence this is lost due to descent of the bladder neck below the pelvic floor muscle. On coughing or sneezing or physical exercise, i.e. when strain is put upon the bladder, an involuntary spurt of urine is released from the bladder. This involuntary urine release is unpleasant and embarrassing. The released urine may irritate the groin region and result in an offensive odour.

Vaginal and rectal prolapse are quite common conditions in females, particularly those who have vaginally delivered one or more children. These conditions may be painful, and uncomfortable. Additionally, sexual intercourse may be impaired by occlusion of the vagina.

It is a generally accepted view that surgical treatment is most appropriate for cure of stress incontinence and vaginal and rectal prolapse. However, in elderly or infirm patients the risk of surgery is too great, so that often these conditions go untreated.

Previously proposed devices to treat incontinence and avoid recourse to surgery have generally been unsatisfactory. Particularly, they are cumbersome, difficult to use, need to be replaced frequently, are inadequate in cases of permanent incontinence and often fail to prevent involuntary urinary leakage.

One previous device, according to US Patent 4139006, to which the preamble of Claim 1 of this invention corresponds consists of an annular body with a protrusion which reduces the urethro-vesicle angle. US Patent 3554184 has a partly internal/partly external member which is held in place by a harness worn around the patient.

One aspect of the present invention has as its object to provide an intra-vaginal device to aid in controlling vaginal and rectal prolapse.

According to this invention there is provided a wholly intra-vaginal device having an aperture therein and including a cradle-like structure,

characterised in that the device comprises a generally U-shaped, convex member having two opposed limbs interconnected by a flexible base portion having the aperture, one of the limbs being adapted to lie in use adjacent and along the anterior vaginal wall and including the cradle-like structure to lift the bladder base and bladder neck lying behind the vaginal wall without closing the urethra, the other limb being adapted to lie in use adjacent and along the posterior vaginal wall, with the aperture disposed in use adjacent the cervix of the uterus.

The base portion is preferably arch-shaped, and is preferably comprised of a resilient material or has resilient material embedded within the arch.

Preferably, the cradle-like structure, which lifts the bladder base and bladder neck, is formed by two protrusions extending from the free end of the limb which lies adjacent the anterior vaginal wall. These protrusions have a depression therebetween. This depression accommodates the anterior vaginal wall and the neck and base of the bladder.

In use, the base portion biases the limbs outwardly to aid in retention of the device in the vagina.

The limb adjacent the posterior vaginal wall preferably has two legs at its free end. These legs are preferably curved and splayed in order to fit over the perineal body for supporting the device in the vagina.

Preferably, the opposing inner surfaces of the two limbs are covered by a spongy deformable material bearing complementary grooves and ridges. This material imitates vaginal mucosa. Sexual intercourse is therefore not affected by the device as the spongy material cannot readily be distinguished by the male partner. Additionally, the grooves and ridges aid in channelling menstrual blood and vaginal secretions through the vagina.

The above device may be used with an intra-vaginal device to aid in controlling urinary incontinence, said device comprising a body having a forward portion to engage an anterior portion of the vaginal wall, and a rear portion to engage a posterior portion of the vaginal wall, and wherein said anterior portion is expandable to apply pressure to the bladder neck to at least partly close the neck.

Preferably the body of the above described intra-vaginal device to aid in controlling urinary incontinence, would consist of a flexible ring defining a central portion substantially closed by means of a diaphragm.

Still further, it is preferred that the above described ring would be adjustable in diameter.

The present invention will now be described by way of example only with reference to the following drawings, in which:

Fig. 1 is a perspective view of the intravaginal

device;

Fig. 2 is a side view of the intra-vaginal

Fig. 3 is an end view of the intra-vaginal device;

Fig. 4 is a schematic view of a sagittal section of the female pelvic organs showing the intra-vaginal device in place;

Fig. 5 is a schematic perspective view of an intra-vaginal device to aid in controlling urinary incontinence;

Fig. 6 is a schematic view of a sagittal section of the female pelvic organs showing the device of Fig. 5 in place.

The intra-vaginal device shown in Fig. 1 is constructed of a flexible material for example a plastic/silicone compound.

The device comprises a base portion 10 which forms an arch 12 of generally "U-shaped" configuration. The base portion 10 may be inherently resilient or may contain a resilient insert. The arch 12 contains an aperture 13 which in use is adjacent the cervix of the uterus. The arch 12 interconnects two opposing limbs 14 and 16. The limb 14 lies adjacent the anterior vaginal wall in use and has at its end two opposed rounded projections 18 having a depression 20 therebetween to form a cradle-like structure.

The limb 16 extending from the arch 12 is of substantially planar construction and has at its forward end a pair of splayed legs 22.

The flexible and resilient nature of the arch 12 enables the device to be readily inserted into the vagina and aids in its retention therein. Particularly, the arch 12 biases the limbs 14 and 16 outwardly, causing them to press against the anterior and posterior walls of the vagina respectively, this holding the device in place.

As shown in Fig. 4, when the device is inserted into the vagina, the limb 14 lies adjacent to and supports the anterior vaginal wall 24 preventing prolapse of the anterior vaginal wall (cystocele) and prolapse caused by the bladder 25 pressing against the anterior vaginal wall 24 (cysto-urethrocele). The outward bias of the limb 14 causes the projections 18 to cradle the anterior vaginal wall 24 and lift the neck and base of the bladder above the pelvic floor muscle thereby causing continence. Additionally, a significant closure of the bladder neck is achieved as is a reduction of the included angle between the urethra and the bladder. These features again increase continence.

The arch 12 supports the cardinal and uterosacral ligaments (not shown) and helps to lift the uterus in the pelvic cavity thereby preventing uterine prolapse. The aperture 13 in the arch 12 lies adjacent the cervix of the uterus.

The limb 16 lies adjacent to and supports the posterior vaginal wall 26, thereby preventing pro-

lapse of the posterior vaginal wall 26 (enterocele) and rectal prolapse (rectocele). The legs 22 of the limb 14 rest on the posterior vaginal wall 26 in the region of the para-rectal fossa 27. The splayed nature of the legs enables them to fit over the perineal body, this aiding in retention of the device in the vagina.

The device may be of different sizes to accommodate different vaginal size. Preferably, those portions of the device contacting the vaginal wall are smeared with Disaestrol (Registered Trade Mark) and Sultril (Registered Trade Mark) cream in order to minimize vaginal irritation.

In a further embodiment of the present invention as shown in Figs. 5 and 6, a small inflatable balloon 28 may be provided between the projections 18. The balloon may be inflated to compress the bladder neck against the pubic symphysis thus closing off the urethra resulting in continence. The balloon 18 may be inflated/deflated by virtue of a small lead connected to the balloon which passes out of the vagina where it can be manipulated by the patient.

The above discussed preferred embodiments of the present invention have the advantage that they may be placed in position by a medical practitioner without anaesthetic, with immediate results achievable.

## Claims

1. A wholly intra-vaginal device having an aperture (13) therein and including a cradle-like structure, characterised in that the device comprises a generally U-shaped, convex member having two opposed limbs (14, 16) interconnected by a flexible base portion (10) having the aperture, one (14) of the limbs being adapted to lie in use adjacent and along the anterior vaginal wall and including the cradle-like structure (18, 20) to lift the bladder base and bladder neck lying behind the vaginal wall without closing the urethra, the other limb (16) being adapted to lie in use adjacent and along the posterior vaginal wall, with the aperture disposed in use adjacent the cervix of the uterus.
2. A device according to claim 1 wherein the base portion (10) is arch-shaped and the device is formed of a resilient material or has resilient material embedded within the arch (12).
3. A device according to claim 1 or 2, wherein said cradle-like structure (18,20) is formed by two protrusions (18) extending from the free end of the limb (14) which lies in use adjacent

the anterior vaginal wall.

4. A device according to claim 3 wherein the protrusions (18) have a depression (20) therebetween.
5. A device according to claim 4 wherein the base portion biases the limbs outwardly to aid in retaining the device within the vagina.
6. A device according to claim 1 wherein the limb (16) adjacent the posterior vaginal wall has two legs (22) at its free end, with the legs being curved and splayed in order to fit over the perineal body for supporting the device in the vagina.
7. A device according to claim 1 wherein the limb (14) which engages the anterior vaginal wall is provided with an expandable member (28) to at least partly close the bladder neck.

#### Revendications

1. Dispositif intégralement intravaginal ayant une ouverture (13) et comprenant une structure analogue à un arceau, caractérisé en ce que le dispositif comprend un élément convexe généralement en forme de U, ayant deux membres opposés (14, 16) reliés entre eux par une partie formant base souple (10) dans laquelle se trouve l'ouverture, l'un (14) des membres étant conçu pour reposer, en fonctionnement, en position adjacente à la paroi vaginale antérieure et le long de celle-ci et comprenant la structure en forme d'arceau (18, 20) pour soulever la base de la vessie et le col de la vessie situés derrière la paroi vaginale sans fermer l'urètre, l'autre membre (16) étant conçu pour reposer, en fonctionnement, en position adjacente à la paroi vaginale postérieure et le long de celle-ci, l'ouverture étant disposée, en fonctionnement, en position adjacente au col de l'utérus.
2. Dispositif selon la revendication 1, dans lequel la partie formant base (10) est en forme d'arc et le dispositif est constitué par une matière élastique ou comprend une matière élastique incorporée dans l'arc (12).
3. Dispositif selon la revendication 1 ou 2, dans lequel ladite structure en forme d'arceau (18, 20) est constituée par deux saillies (18) qui s'étendent depuis l'extrémité libre du membre (14) qui, en fonctionnement, est adjacent à la paroi vaginale antérieure.

4. Dispositif selon la revendication 3, dans lequel un évidement (20) est situé entre les saillies (18).

5. Dispositif selon la revendication 4, dans lequel la partie formant base pousse les membres vers l'extérieur pour favoriser le maintien du dispositif à l'intérieur du vagin.

6. Dispositif selon la revendication 1, dans lequel le membre (16) adjacent à la paroi vaginale postérieure comporte deux branches (22) à son extrémité libre, les branches étant incurvées et évasées de manière à s'adapter sur le noyau fibreux central du périnée pour soutenir le dispositif dans le vagin.

7. Dispositif selon la revendication 1, dans lequel le membre (14) qui est en contact avec la paroi vaginale antérieure est muni d'un élément extensible (28) de manière à fermer au moins partiellement le col de la vessie.

#### Patentansprüche

1. Vollständig intravaginale Vorrichtung, welche eine Öffnung (13) sowie eine gabelartige Struktur umfaßt, dadurch gekennzeichnet, daß die Vorrichtung ein im wesentlichen U-förmiges, konvexes Teil mit zwei gegenüberliegenden Armen (14, 16) aufweist, die durch einen elastischen Basisbereich (10), der die Öffnung (13) aufweist, miteinander verbunden sind, wobei einer (14) der Arme so ausgebildet ist, daß er beim Gebrauch auf und längs der vorderen Vaginalwand anliegt und zusammen mit der gabelartigen Struktur (18, 20) die hinter der Vaginalwand liegende Blasenbasis sowie den Blasenansatz anhebt, ohne die Harnröhre zu verschließen, während der andere Arm (16) so ausgebildet ist, daß er beim Gebrauch auf und längs der hinteren Vaginalwand anliegt, und wobei die Öffnung beim Gebrauch am Gebärmutterhals angeordnet ist.
2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß der Basisbereich (10) bogenförmig ist und die Vorrichtung aus elastischem Material geformt ist oder im Bereich des Bogens (12) eingesetztes elastisches Material besitzt.
3. Vorrichtung nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die gabelartige Struktur (18, 20) durch zwei Fortsätze (18) gebildet wird, die vom freien Ende des Armes (14), der beim Gebrauch an der vorderen Vaginalwand anliegt, abstehen.

4. Vorrichtung nach Anspruch 3, dadurch gekennzeichnet,  
daß die Fortsätze (18) zwischen sich eine Einsenkung (20) besitzen. 5
5. Vorrichtung nach Anspruch 4, dadurch gekennzeichnet,  
daß der Basisbereich die Arme nach auswärts spannt, um die Halterung der Vorrichtung in der Vagina zu unterstützen. 10
6. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet,  
daß der Arm (16) an der hinteren Vaginawand an seinem freien Ende zwei Schenkel (22) besitzt, die derart bogenförmig und ausgeschrägt sind, daß sie über das Perineum passen, um die Vorrichtung in der Vagina abzustützen. 15  
20
7. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet,  
daß der an der vorderen Vaginawand anliegende Arm (14) ein expandierbares Glied (28) aufweist, um den Blasen Hals zumindest teilweise zu schließen. 25

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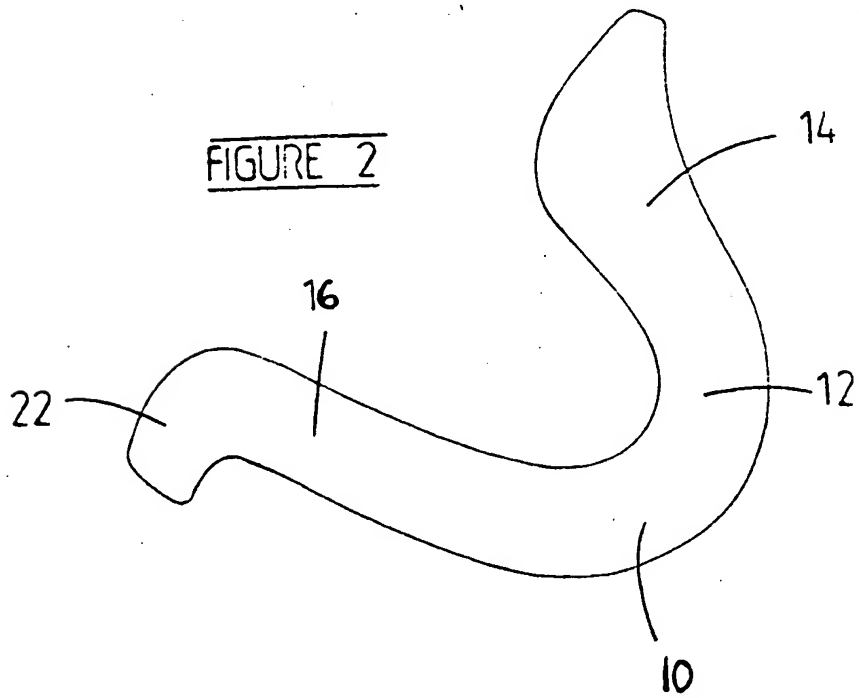
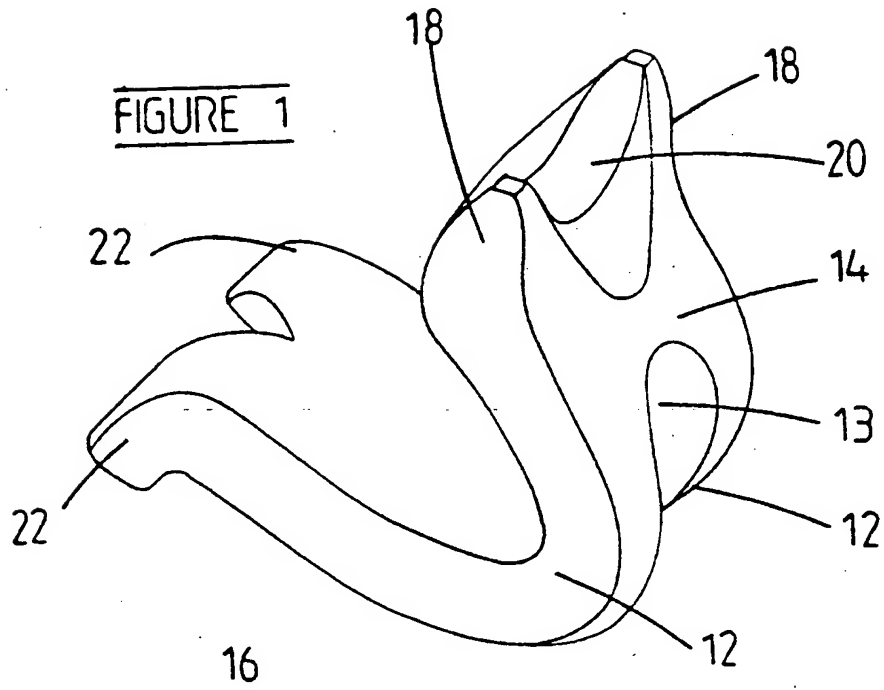
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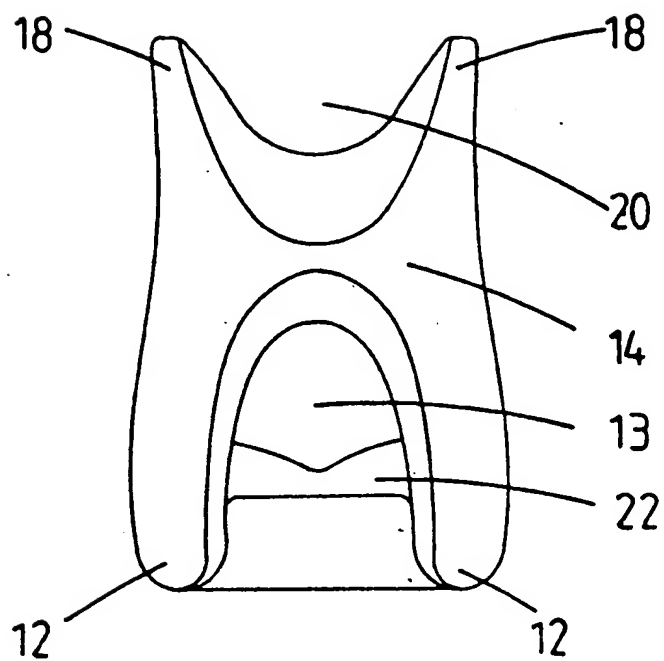


FIGURE 3

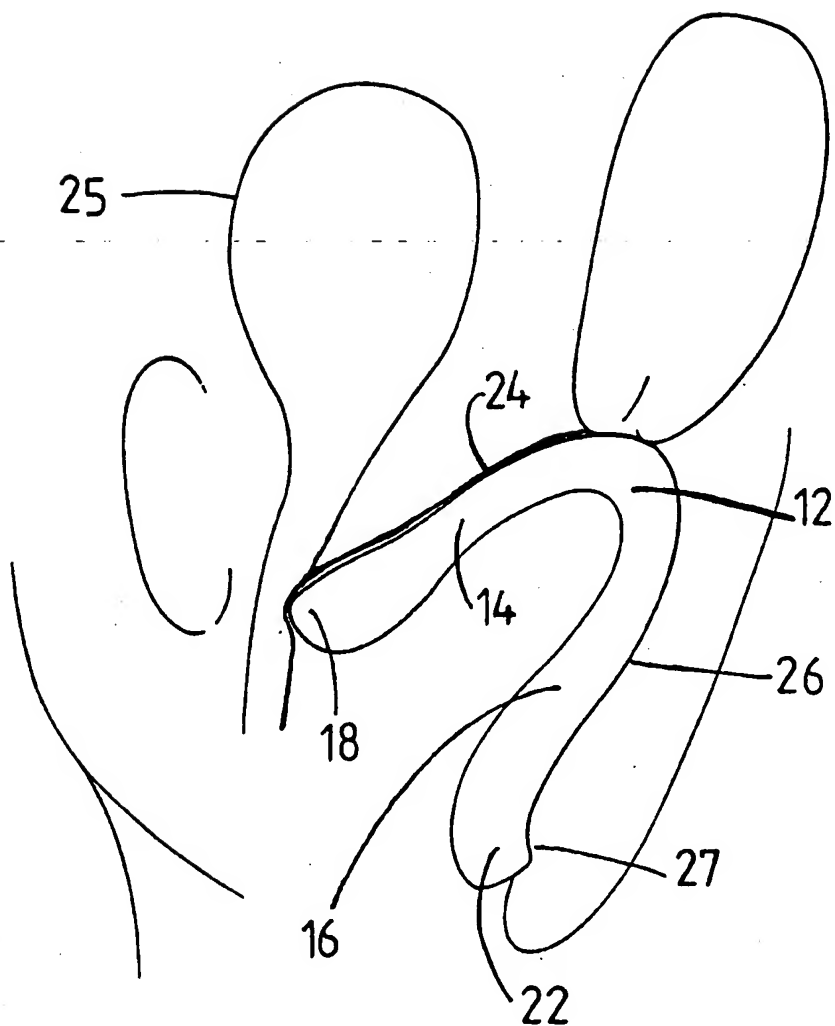


FIGURE 4



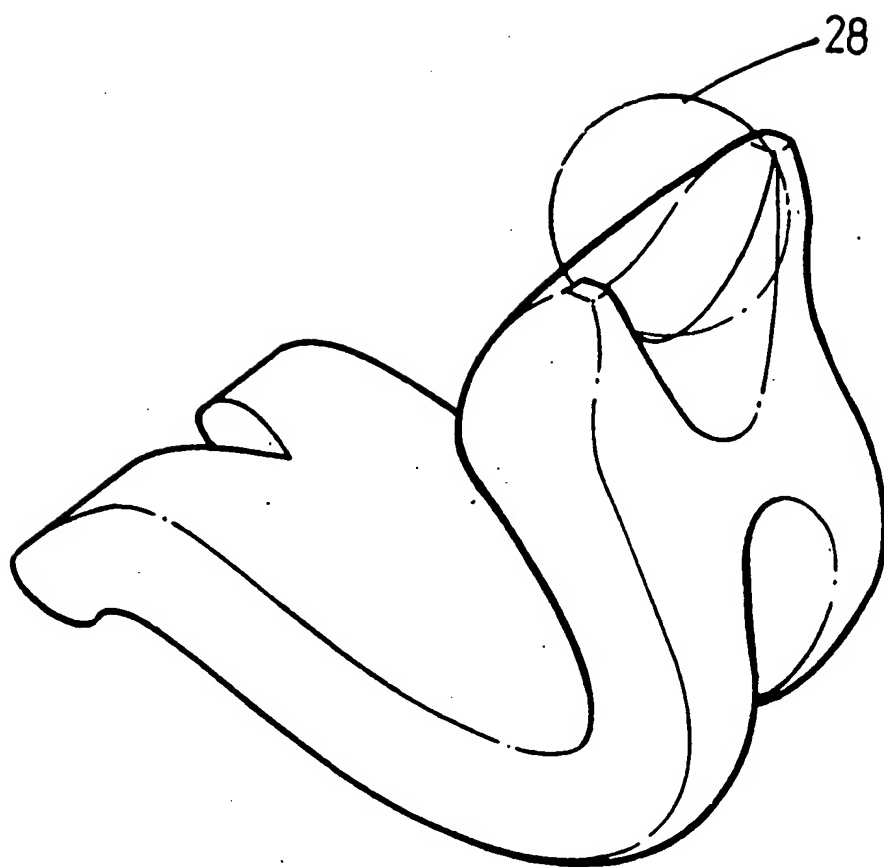


FIGURE 5

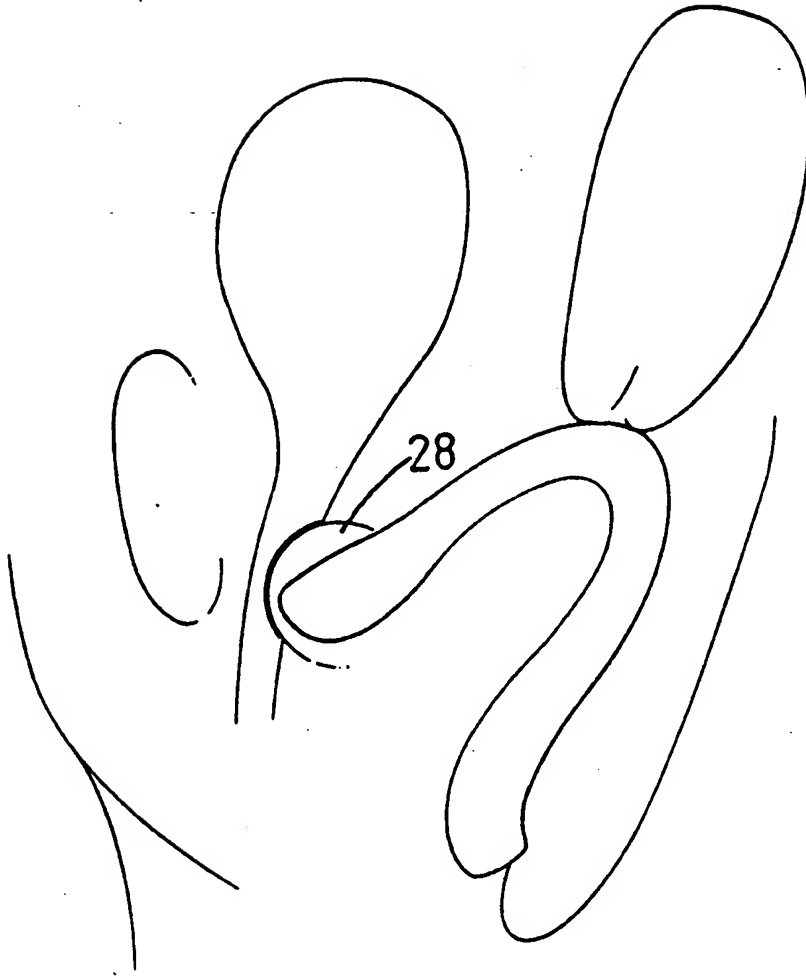


FIGURE 6